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| 09/981,124 | 10/17/2001 | Allan Green | 26-98A | 9503 |
| 7590 07/09/2008 | | | | |
| John P. White, ESQ COOPER & DUNHAM LLP 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036 | | EXAMINER MCELWAIN, ELIZABETH F | | |
| | | ART UNIT PAPER NUMBER | | |
| | | 1638 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary

| | | |
|--|-------------------------------------|--|
| Application No. 09/981,124 | Applicant(s) GREEN ET AL. | |
| Examiner Elizabeth F. McElwain | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 March 2008.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 41-43 and 50-67 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 41-43 and 50-67 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/21/08.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

The amendment filed March 21, 2008 has been entered.

Claims 1-40 and 44-49 are cancelled

Claims 50, 54, 55 and 59 are currently amended.

Claims 62-67 are newly submitted.

Claims 41-43 and 50-67 are pending and are examined on the merits.

Claim Objections

1. Claims 55, 59, and 67, and 56 and 60 dependent thereon, are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation that the nucleic acid is obtained from a plant capable of producing epoxy fatty acids prior to the process for producing the transgenic plant fails to further limit the claims from which they depend. Please note that claims to a method of isolating a nucleic acid from a plant possessing the capacity to synthesize epoxy fatty acids and producing a gene construct would be considered a new method non-elected by original presentation.
2. Claim 67 is objected to for the recitation of "the cell of tissue", which should read "the cell or tissue". Correction is requested.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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2. Claims 55, 56, 59, 60 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 55, 59 and 67, and claims 56 and 60 dependent thereon, are indefinite and confusing in the recitation of “possessing the genetic capacity to synthesize epoxy fatty acids”, given that it is unclear what would constitute such a genetic capacity or what “genetic capacity” means, and the specification fails to define or clarify the use of this term. The claims are further confusing in the recitation of “further comprising, prior to transforming the cells or tissues, obtaining the nucleic acid. . .”, given that the claimed methods from which these claims depend require that the nucleic acid was isolated and in a gene construct for transformation of a cell or tissue of a plant. This phrase appears to be redundant or otherwise, it is unclear what is intended by this phrase.

4. Applicants’ arguments filed March 21, 2008 have been fully considered but they are not persuasive. Applicants argue that the amendment of the claims should overcome the rejection. The Examiner maintains that the initial rejection under 112, second paragraph is withdrawn in view of the amendment of the claims. However, the claims remain indefinite for the reasons set forth above.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 55, 59, 60 and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. Claims 41-43 and 50-67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic *Arabidopsis* and flax plants that are transformed with a nucleic acid of SEQ ID NO: 1 or a nucleic acid encoding the delta-12 epoxygenase of SEQ ID NO: 2, does not reasonably provide enablement for any transgenic plant species transformed with a nucleic acid encoding a polypeptide having the recited histidine rich regions and having at least 60% identity to SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons set forth in the last office action.

8. Applicants' arguments filed March 21, 2008 have been fully considered but they are not persuasive. Applicants argue that the rejection is misplaced since it is focused on product claims, while the claims are drawn to process claims. The Examiner maintains that the rejection is based on the specification being non-enabling for how to make and/or use the invention.

9. Applicants also argue that a working example is provided for cloning epoxygenase genes from *Crepis palaestina* and expressing said genes in *Arabidopsis* to produce plants with increased concentrations of vernolic acid. Applicants further assert that undue experimentation

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would not be required to practice the claimed process, since the procedures of transforming and regenerating plants are well known in the art.

10. The Examiner maintains that the specification only discloses a method of producing an Arabidopsis plant or a flax plant transformed with a nucleic acid of SEQ ID NO: 1 or a nucleic acid encoding the delta-12 epoxygenase of SEQ ID NO: 2, wherein the resultant plant produced by the process has increased vernolic acid as compared to a non-transformed plant. However, the specification does not provide working examples of any plants transformed with any of the multitude of sequences encompassed by the claims, and there is no guidance with regard to the functional activity of any of the other sequence encompassed by the claims or what phenotypic characteristics the resultant plants would have. There is no teaching with regard to how one would use a method of producing a plant by transforming said plant with a nucleic acid sequence encoding a polypeptide with undetermined activity, wherein the transformed plant has undetermined phenotypic characteristics. The specification is not enabling for the full scope of the claims for the reasons set forth above and in the previous office actions.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 41, 42, 57, 58, 59, 61, 62 are rejected under 35 U.S.C. 102(e) as being anticipated by DeBonte et al.

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13. DeBonte et al teach transformation of Brassica napus (oilseed rape) with SEQ ID NO : 1, which is at least 74.3% identical to SEQ ID NO : 2 of the present application and wherein the prior art sequence further comprises three histidine boxes as specified in the claims. See the prior art SEQ ID NO: 1 at amino acids 105 to 109; 141 to 145; and 316 to 320, for example. See also columns 11-18, for example.

14. Applicants' arguments filed March 21, 2008 have been fully considered but they are not persuasive. Applicants argue that a sequence alignment is provided as Exhibit B that shows that an alignment of the amino acid sequences of SEQ ID NO: 2 of the present application with SEQ ID NO: 2 of DeBonte et al by the BLAST sequence alignment program resulted in only 56% identity, while the claims are drawn to at least 60% identity. The Examiner maintains that the claims are drawn to a method of using a nucleic acid that encodes a polypeptide wherein the polypeptide is at least 60% identical to a sequence of amino acids set forth in SEQ ID NO: 2, wherein there are regions of consecutive amino acids in SEQ ID NO: 2 of the present application that are 60% identical to the amino acid sequence of SEQ ID NO: 2 of the prior art. The claim is not limited to "**the** sequence of amino acids set forth in SEQ ID NO: 2", which would be read as the full length sequence of SEQ ID NO: 2. In addition, no parameters for determining sequence identity are set forth in the claims, and the particular alignment and percent identity results are dependent upon the alignment program and choices of gap length and word size, for example. Therefore, the Examiner maintains that the rejection is proper.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EFM

/Elizabeth F. McElwain/

Primary Examiner, Art Unit 1638